

Appln No.: 08/822,186

Amendment dated August 4, 2004

In Response to Examiner's Advisory Action dated July 14, 2004

REMARKS

Claims 1, 3-6, 8, 9, 11-25, 31-33 and 35-38 are pending in this application. Claims 2, 7, 10, 26-30 and 34 are canceled. Claims 6, 9 and 14 are withdrawn as being drawn to nonselected species. Upon allowance of the generic claim, applicants will request rejoinder of claims 6, 9 and 14.

Applicants have amended claim 1 to recite that the bone morphogenetic protein is selected from the group consisting of OP1, OP2, OP3, BMP2, BMP3, BMP4, BMP5, BMP6, BMP9, BMP10, BMP11, BMP12, BMP15, BMP16, DPP, Vgl, 60A protein, GDF-1, GDF3, GDF5, GDF6, GDF7, GDF8, GDF9, GDF10 and GDF11. Support for this claim is provided, e.g., on page 1, lines 15-24; page 22, lines 13-17; and in original claim 2 as filed.

Applicants have amended claim 3 to delete the recitation of "variants thereof having conservative amino acid substitutions and substantially similar osteogenic activity."

Applicants have amended claim 4 to be in independent form to recite a device for inducing local bone and cartilage

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formation comprising a bone morphogenetic protein comprising an amino acid sequence having at least 70% homology with the C-terminal 102-106 amino acids, including the conserved seven cysteine domain, of human OP1; a non-synthetic, non-polymeric matrix selected from the group consisting of collagen, apatites, hydroxyapatites, tricalcium phosphate, and admixtures thereof; and a binding agent selected from the group consisting of cellulose and salts thereof; wherein said bone morphogenetic protein is capable of inducing repair of endochondral bone when implanted together with a matrix in a mammal. Support for this claim is provided, e.g., on page 1, lines 15-24; page 22, lines 13-17 and lines 20-23; and in original claim 4 as filed.

Applicants address the Examiner's July 14, 2004

Advisory Action below:

"Bone morphogenetic protein"

The Examiner states that the term "bone morphogenetic protein" raises the issue of new matter. The Examiner also states that it would not overcome the rejections based upon the term "osteogenic protein".

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Applicants respectfully submit that in his March 4, 2004 Final Office Action, the Examiner rejected the term "osteogenic protein" under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner stated that the term "osteogenic protein" "at best only describes what an 'osteogenic protein' does, rather than of what it is." Moreover, the Examiner stated "[i]f Applicants intend the 'osteogenic protein' of the present claims to only encompass a BMP subgroup of the TGF- $\beta$  superfamily of growth factors, then Applicants should have no hesitation in importing the structural and functional limitations that define or describe a BMP subgroup of the TGF- $\beta$  superfamily of growth factors into the present claims."

Applicants have further amended the claims to recite specific BMPs. The specification provides ample written description for the claims as amended (see, e.g., on page 1, lines 15-24; page 22, lines 13-17 and lines 20-23). Accordingly, applicants request that the Examiner withdraw the rejection.

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Restriction and/or Election Requirement

The Examiner has maintained the restriction and/or election requirement of claims 1-6, 8, 9, 11-25, 31-33, 35 and 36 in his Advisory Action. Applicants traverse.

Applicants respectfully submit that in neither his Final Office Action of March 4, 2004 nor in his July 14, 2004 Advisory Action did the Examiner identify the restriction and/or election or the basis for it. Applicants submit that both rejections are improper because they do not provide applicants with any guidance as to what the Examiner is requesting. Accordingly, applicants are unable to respond beyond stating that they stand ready to respond to any restriction and/or election requirements that the Examiner may issue.

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CONCLUSION

In view of the foregoing remarks and amendments, applicants request that the Examiner favorably reconsider this application and allow the claims pending herein. If the Examiner believes that a telephone conference would expedite allowance of this application, he is invited to telephone the undersigned at any time.

Respectfully submitted,

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